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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,893	01/17/2001	Shih-Chieh Hung	11709-003001	6011

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EXAMINER	
GARVEY, TARA L	
ART UNIT	PAPER NUMBER
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/761,893	HUNG ET AL.	
	Examiner	Art Unit	
	Tara L. Garvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6,7,9-20,23 and 32* is/are pending in the application.

4a) Of the above claim(s) *12-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7,9-11,23 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*. See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1,4,6,7,9-20,23 and 32 are pending. Claims 12-20 are withdrawn from consideration. Receipt is acknowledged of an amendment filed on September 28, 2006 in which claims 1, 9 and 23 were amended. Any rejection of record in the previous office actions not addressed herein is withdrawn.

Response to Amendment

Claim Objections

The objection of claims 9 and 23 is withdrawn in view of applicants' amendment.

Response to Arguments

Applicant's arguments filed September 23, 2006 have been fully considered but they are not persuasive.

(1) In regard to the statement in the office action that "since many type of cells, other than MSC have the ability to adhere to a tissue culture plate, it is unlikely that the cell culture device described will only allow MSCs to adhere to the plate when a cell culture mixture other than bone marrow is used, applicants' argue that it has been well reported that MSC are plastic-adherent cells. Further, applicant sites various references to demonstrate that MSC from bone marrow can be isolated based on their plastic adherence property.

In response to applicant's arguments, as stated on page 9 of the Office Action mailed on September 11, 2006, the applicant's have established the ability to isolate

MSCs based on plastic-adherence when the sour of the MSCs is bone marrow. All the reference cited in support of applicants' argument described isolation of MSC from bone marrow.

(2) Applicants' argue that the main purpose of the pore is to have the small-sized hematopoietic cells or blood cells pass through and as indicated by the examiner, the skilled person in the art would realize the sizes of hematopoietic cells or blood cells range from 1.5μM to 20μM. Therefore, the skilled person would know to use a pore size in this range and applicants have amended the claims to a range from 1.5μM to 20μM. Furthermore, the blood cells as well as cells other than MSCs will not adhere on plastic plates and the cells other than MSC will deform and pass through the pore size of about 1.5μM. Therefore, it does not require to do a "large amount of experimentation" to determine the pore size of the culture device.

In response to applicants' arguments, the applicant had not provided any guidance on selecting an acceptable range within the disclosed 0.4μM to 40μM pore size that would meet all the limitations of the claimed method. Further, the claims are presently amended to exclude the smaller pore sizes.

(3) Applicants' argue that the pore size ranging from 1.5μM to 20μM meets the written description requirement as the Examiner pointed in the Office Action. Further, applicant's cite In re Wertheim (CCPA 1976) to demonstrate that an original specification included a range of 25%-60% and specific examples of 36% and 50%. A limitation to between 35% and 60% did meet the description requirement. Further, the examiner indicated that the size of a blood cell ranges from 1.5μM to 20μM as indicated

by the examiner in prior art and would lead those skilled in the art to make or use the invention.

First in regard to written description of a pore size ranging from 1.5μM to 20μM, the Examiner did not indicate that this limitation would meet the written description requirement. Further, the foundation of the rejection under written description is not a matter of being able to make and use the invention, therefore the ability of one of ordinary skill in the art to choose a pore size between 1.5μM to 20μM is irrelevant. In terms of the applicant's interpretation of In re Wertheim case, the examiner does not agree. This case demonstrated that narrowing the claims when there is no support in the originally filed disclosure is a violation of written description. The applicant is directed to MPEP 2163.05 for examples of the relationship between claimed ranges and the written description requirement. Excerpts from this section serving as examples are the following: (a) The failure to meet the written description requirement of 35 U.S.C. 112, first paragraph, commonly arises when the claims are changed after filing to either broaden or narrow the breadth of the claim limitations, or to alter a numerical range limitation or to use claim language which is not synonymous with the terminology used in the original disclosure. To comply with the written description requirement of 35 U.S.C. 112, para. 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. See MPEP § 2163 for examination guidelines pertaining to the written description requirement. (b) The introduction of claim changes which involve narrowing the claims by introducing elements or limitations

which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g.,Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir.1996) (a "laundry list" disclosure of every possible moiety does not constitute a writtendescription of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species). (c) With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of"25%- 60%" and specific examples of "36%" and "50%." A corresponding new claim limitation to "at least 35%" did not meet the description requirement because the phrase "at least" had no upper limit and caused the claim to read literally on embodiments outside the "25% to 60%" range, however a limitation to "between 35% and 60%" did meet the description requirement. The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir.1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species).

(4) Applicants' state that the key point of the invention is "the mesenchymal stem cells retain and adhere onto the upper plate and the other small-sized cells pass through the pores to the power plate base."

In response, the summary of applicants' invention is acknowledged.

(5) Applicants' state that this application combines the characteristics of large size and plastic adherence to result in a "novel, simple, effective and economic method of isolating MSCs." In one embodiment, a cell population of greater than 98% human MSC can be obtained and proliferate without differentiation. This application is the first to combine these two features.

In response, the summary of applicants' invention is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 6, 7, 9-11 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recovering mesenchymal stem cells from bone marrow, does not reasonably provide enablement for recovery of mesenchymal stem cells from any source for reasons of record as set forth in the office action mailed on September 11, 2006. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. **In order to have this rejection**

withdrawn, applicant may want to place the limitation of bone marrow aspirate from claim 23 in independent claim 1.

Applicant's arguments are addressed above.

Claims 1, 4, 6, 7, 9-11 and 32 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recovering mesenchymal stem cells from bone marrow, does not reasonably provide enablement for recovery of mesenchymal stem cells from any source for reasons of record as set forth in the office action mailed on September 11, 2006 and above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

New Grounds of Rejection

This new rejection is necessitated by applicant's amendment of the claims.

Claim Rejections - 35 USC § 112

Claims 1, 4, 6, 7, 9-11, 23 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This a rejection for new matter. This rejection was made of record in the office action mailed on December 16, 2005 and maintained in the office action mailed on September 11, 2006. The rejection is repeated below in modified form to address the amended**

claims. In order to have this rejection withdrawn, applicant may want to remove the pore size range from claim 1.

In a method of recovering mesenchymal stem cells from a mixture of cells, the specification describes a culture device that comprises a plate with pores where the "pore size ranges from about 0.4 to 40 microns" on page 7, lines 28-29.

The specification does not describe a cell culture device for recovering mesenchymal stem cells from a mixture of cells in which the pore size ranges from 1.5 to 20 microns. Thus, the newly added limitation to claim 1 constitutes new matter.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey, Ph.D.
Examiner
Art Unit 1636

TLG

CELINE QIAN, PH.D.
PRIMARY EXAMINER